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(54) **MITRAL SPACER**

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CPC A61F 2/24; A61F 2/2412; A61F 2/2418

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See application file for complete search history.

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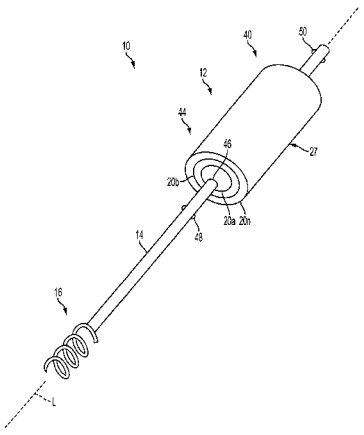
(57) **ABSTRACT**

A heart valve implant may include a shaft and an anchor configured to be coupled to an end of the shaft. A spacer may be coupled to a portion of the shaft and comprise a plurality of individual segments including a first and at least a second individual segment. The first segment may be coupled to the shaft. The second segment may be coupled to at least a portion of an exterior surface of the first segment and may have at least one cross-section dimension which is greater than an internal cross-sectional dimension of a delivery lumen. Additional segments may be coupled to an inner, adjacent segment. The segments may include a collapsible body portion to facilitate percutaneously delivery through a lumen. The segments may define an outer surface of the spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through the heart valve in a closed position.

13 Claims, 10 Drawing Sheets



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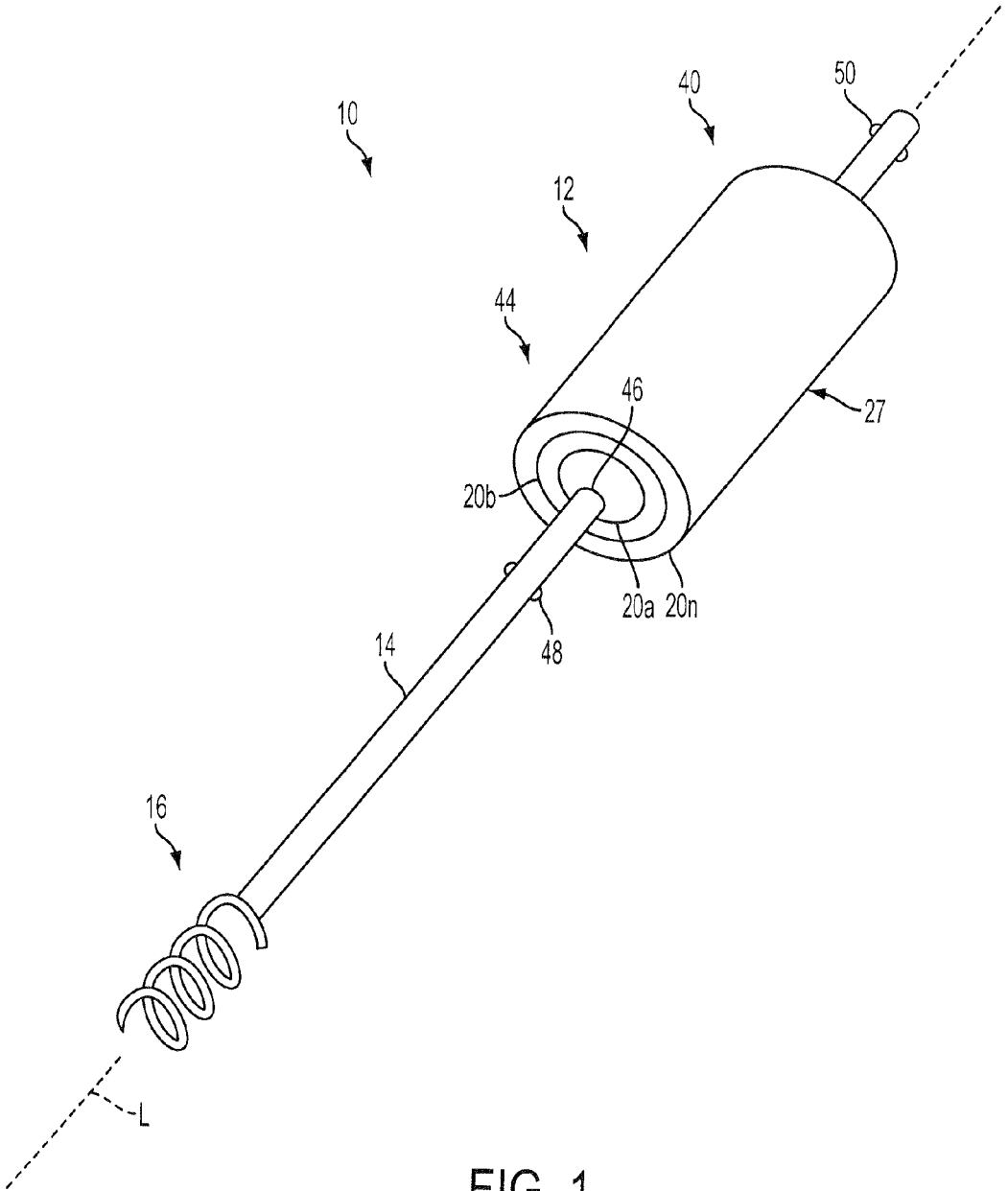

FIG. 1

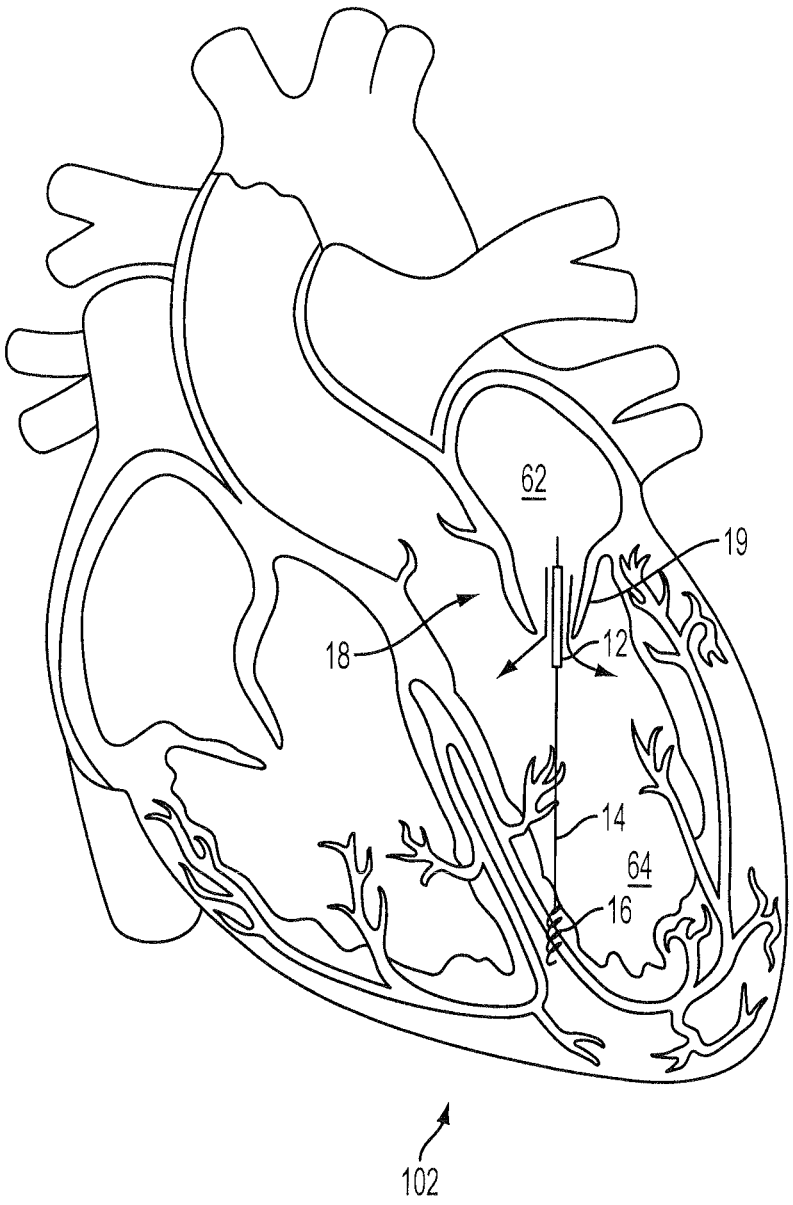

FIG. 2

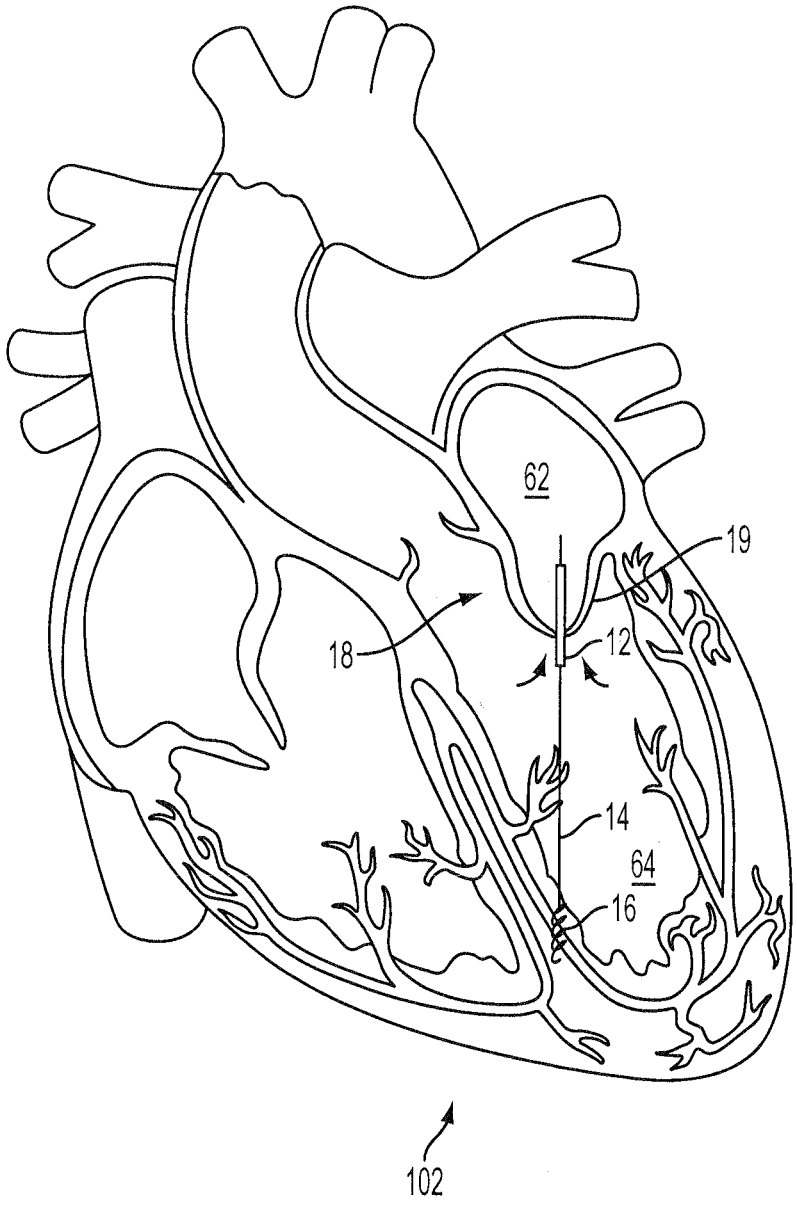

FIG. 3

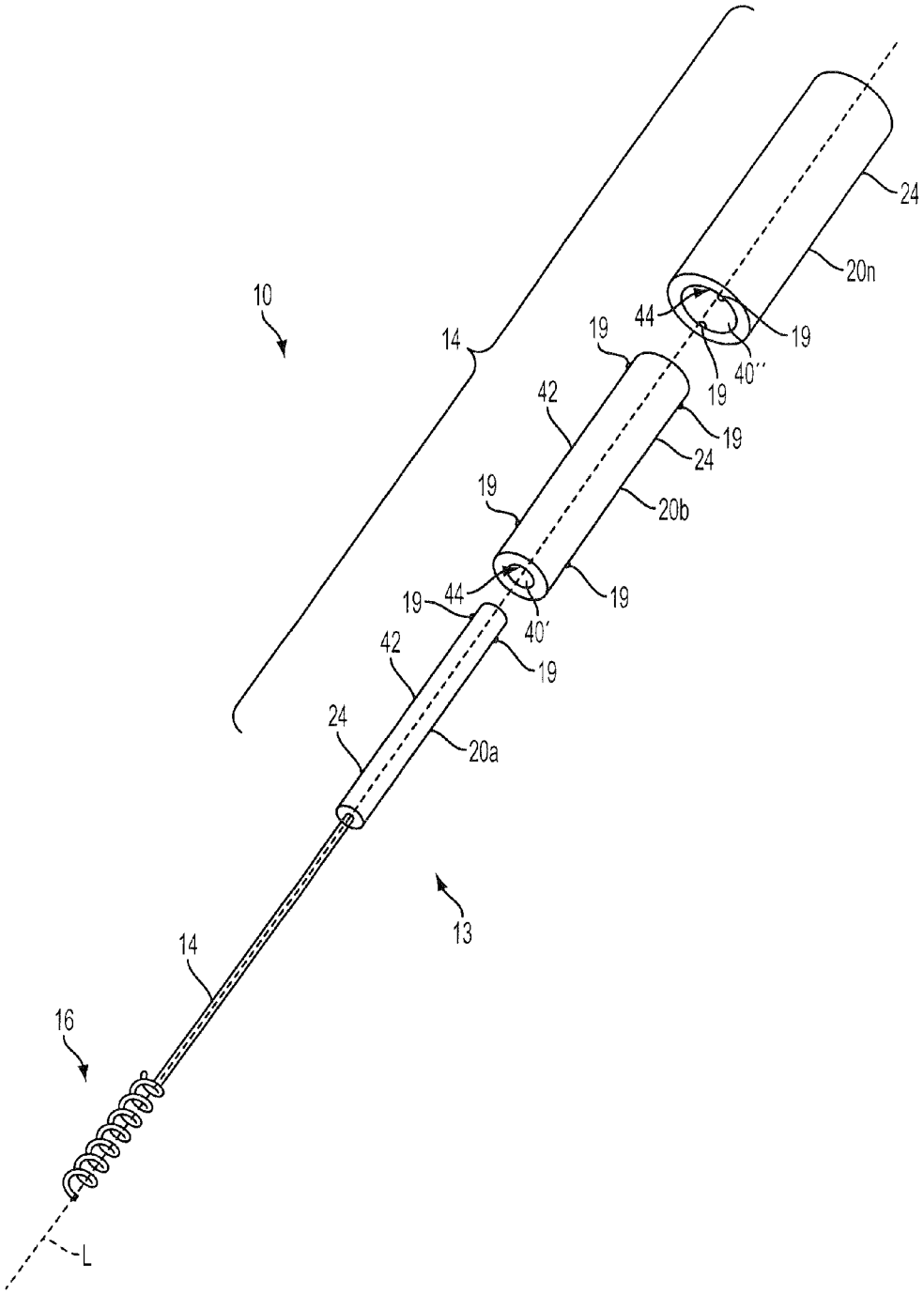

FIG. 4

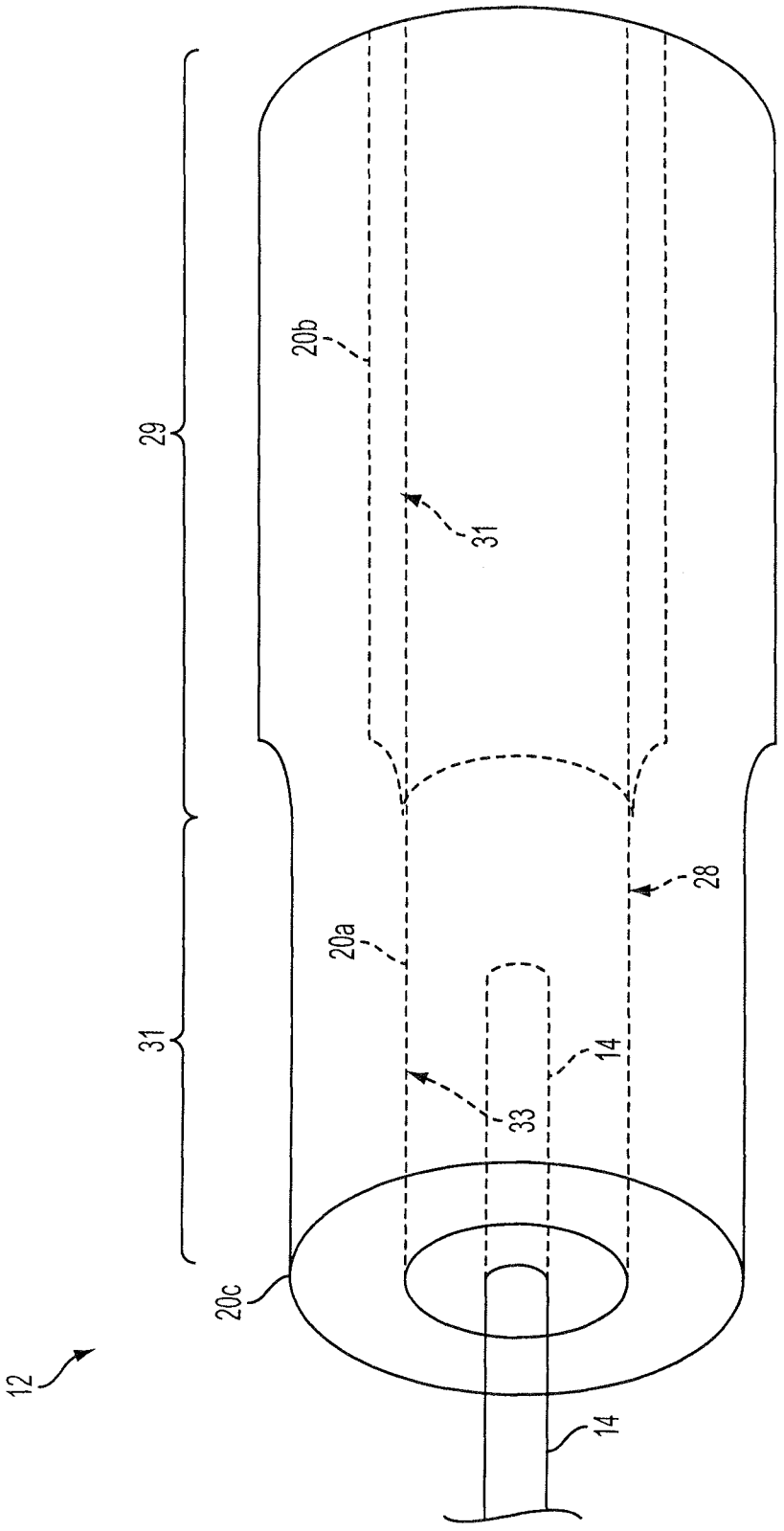

FIG. 5

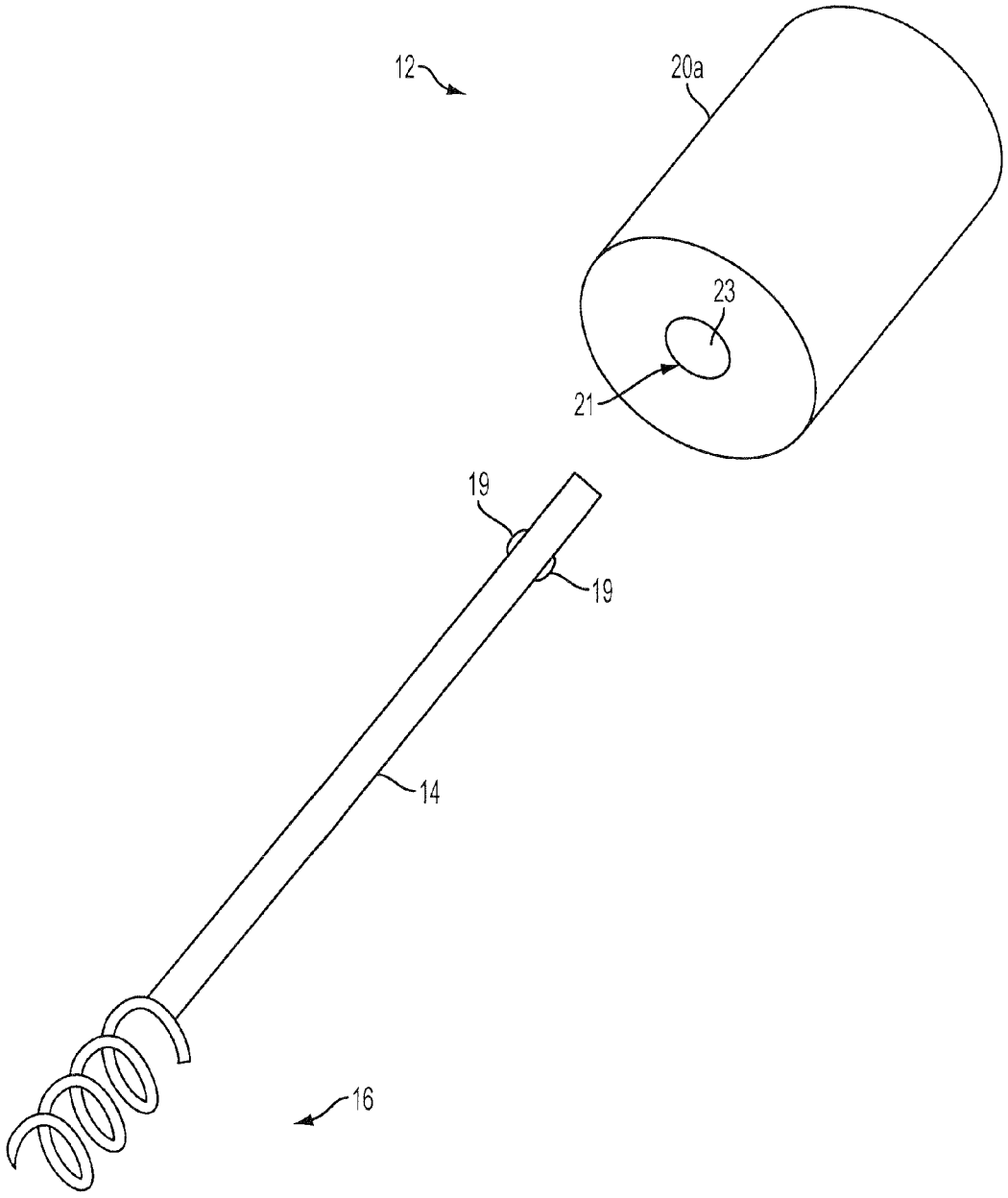

FIG. 6

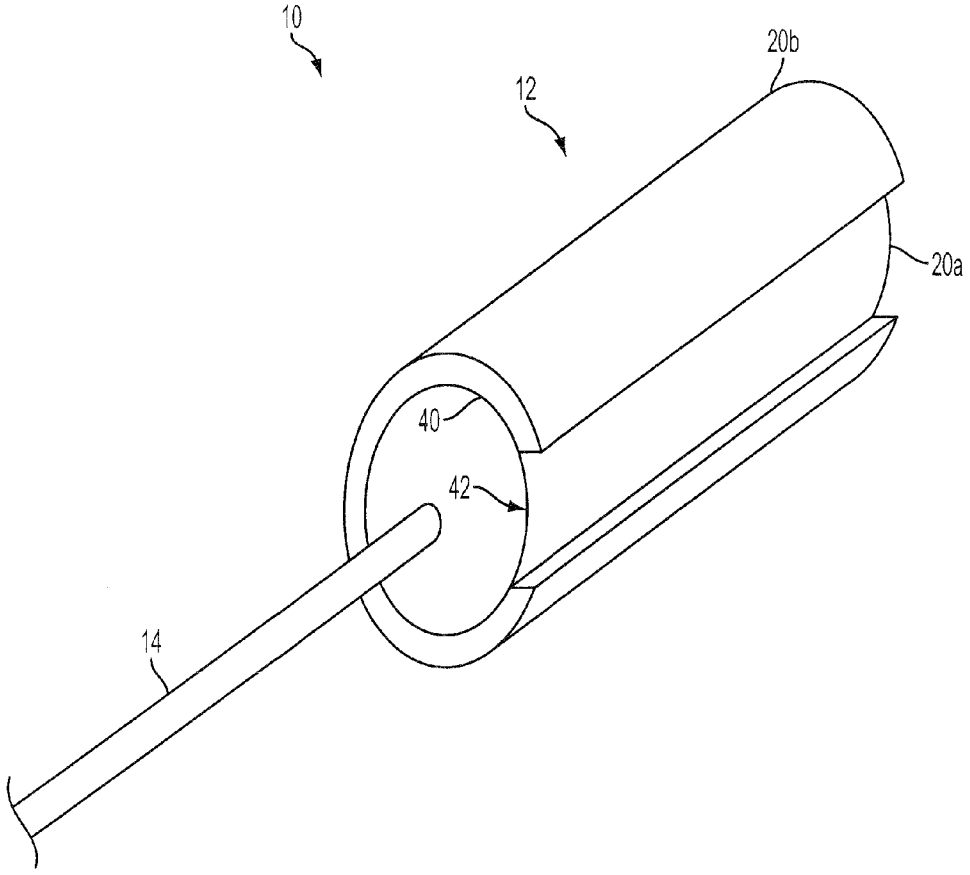

FIG. 7

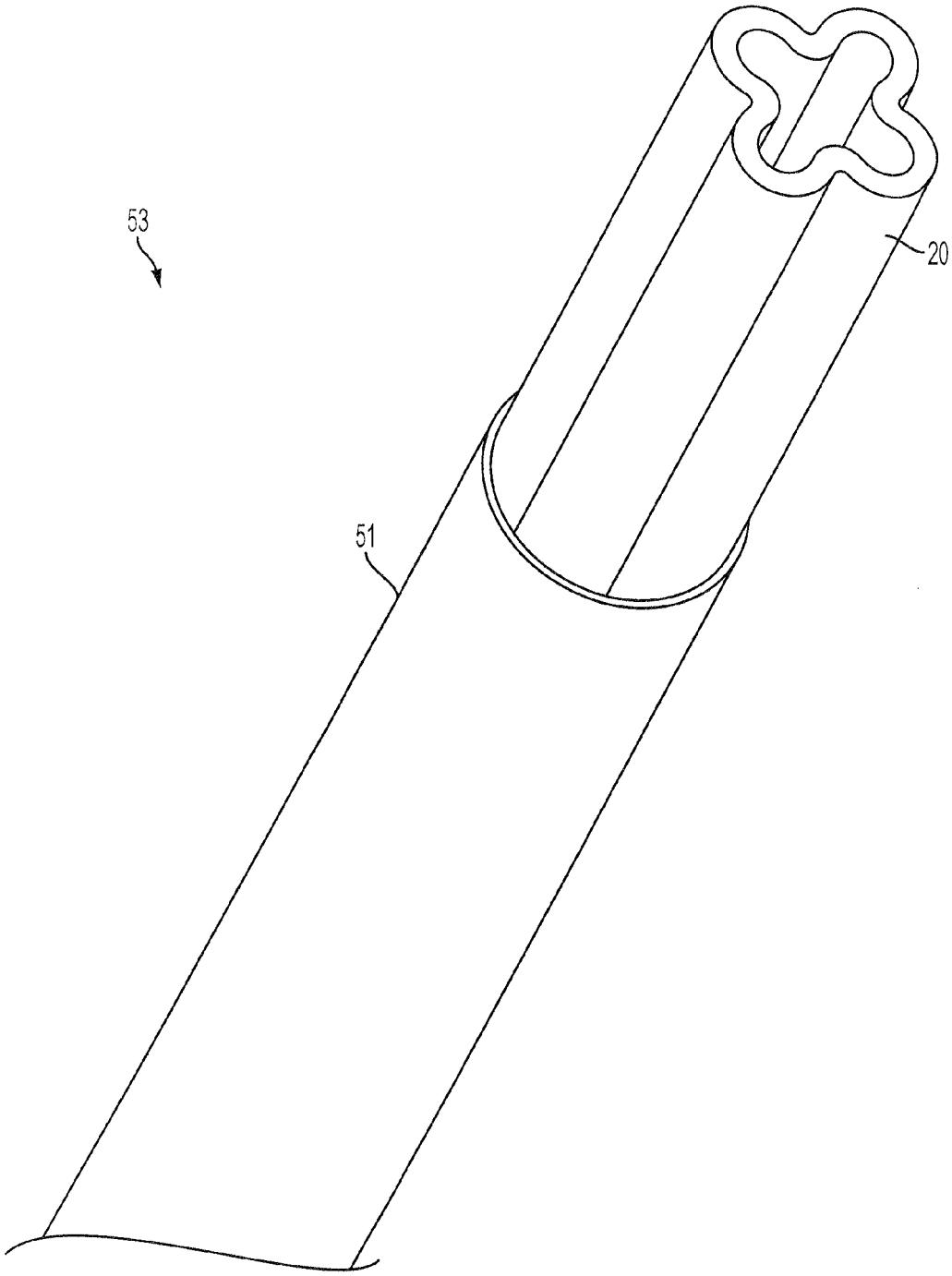

FIG. 8

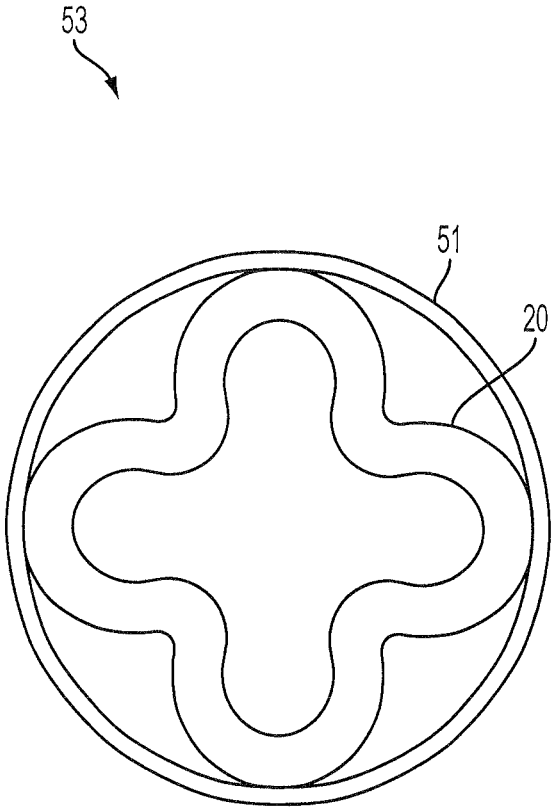

FIG. 9

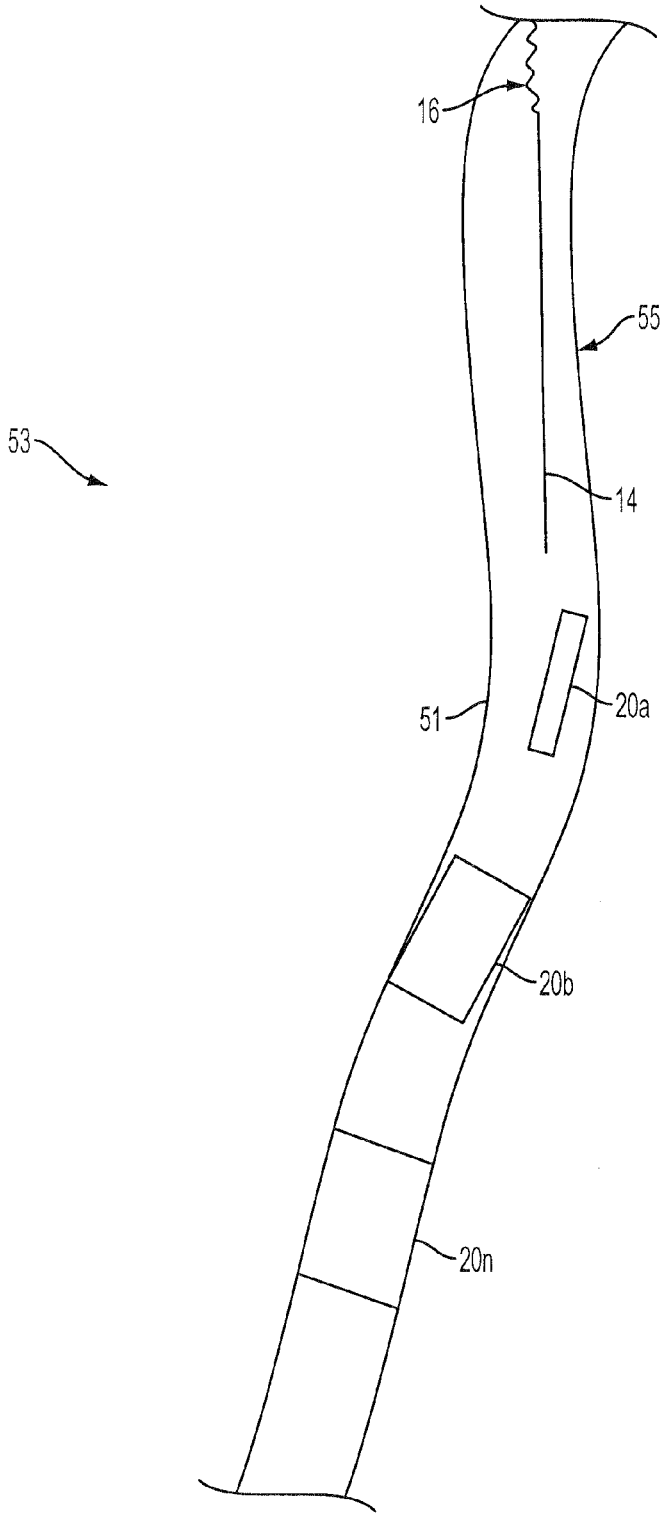

FIG. 10

MITRAL SPACER

CROSS-REFERENCE TO RELATED APPLICATION

The subject application is a continuation of U.S. patent application Ser. No. 12/872,228 (now U.S. Pat. No. 8,486,136) filed Aug. 31, 2012 which is 5 a continuation of U.S. patent application Ser. No. 11/940,674 (now U.S. Pat. No. 7,785,366) filed Nov. 15, 2007, which is a continuation-in-part of U.S. patent application Ser. No. 11/258,828 (now U.S. Pat. No. 8,092,525) filed, entitled "Heart Valve Implant" filed on Oct. 26, 2005, all of which are hereby incorporated by reference.

FIELD

The present disclosure relates to the repair and/or correction of dysfunctional heart valves, and more particularly pertains to heart valve implants and systems and methods for delivery and implementation of the same.

BACKGROUND

A human heart has four chambers, the left and right atrium and the left and right ventricles. The chambers of the heart alternately expand and contract to pump blood through the vessels of the body. The cycle of the heart includes the simultaneous contraction of the left and right atria, passing blood from the atria to the left and right ventricles. The left and right ventricles then simultaneously contract forcing blood from the heart and through the vessels of the body. In addition to the four chambers, the heart also includes a check valve at the upstream end of each chamber to ensure that blood flows in the correct direction through the body as the heart chambers expand and contract. These valves may become damaged or otherwise fail to function properly, resulting in their inability to properly close when the downstream chamber contracts. Failure of the valves to properly close may allow blood to flow backward through the valve resulting in decreased blood flow and lower blood pressure. Mitral regurgitation is a common variety of heart valve dysfunction or insufficiency.

Mitral regurgitation occurs when the mitral valve separating the left coronary atrium and the left ventricle fails to properly close. As a result, upon contraction of the left ventricle blood may leak or flow from the left ventricle back into the left atrium, rather than being forced through the aorta. Any disorder that weakens or damages the mitral valve can prevent it from closing properly, thereby causing leakage or regurgitation. Mitral regurgitation is considered to be chronic when the condition persists rather than occurring for only a short period of time.

Regardless of the cause, mitral regurgitation may result in a decrease in blood flow through the body (cardiac output). Correction of mitral regurgitation typically requires surgical intervention. Surgical valve repair or replacement is carried out as an open heart procedure. The repair or replacement surgery may last in the range of about three to five hours, and is carried out with the patient under general anesthesia. The nature of the surgical procedure requires the patient to be placed on a heart-lung machine. Because of the severity/complexity/danger associated with open heart surgical procedures, corrective surgery for mitral regurgitation is typically not recommended until the patient's ejection fraction drops below 60% and/or the left ventricle is larger than 45 mm at rest.

BRIEF DESCRIPTION OF THE DRAWINGS

Features and advantage of the claimed subject matter will be apparent from the following description of embodiments consistent therewith, which description should be considered in conjunction with the accompanying drawings, wherein:

FIG. **1** is a perspective view of an embodiment of a mitral valve implant consistent with the present disclosure;

FIG. **2** depicts an embodiment mitral valve implant consistent with the present disclosure implanted within a heart in an open position;

FIG. **3** depicts an embodiment mitral valve implant consistent with the present disclosure implanted within a heart in a closed position;

FIG. **4** is a perspective view of the mitral valve implant shown in FIG. **1** in an unassembled state consistent with the present disclosure;

FIG. **5** is a cross-sectional view of another embodiment of the spacer segment consistent with the mitral valve implant according to the present disclosure;

FIG. **6** is a perspective view of another embodiment of the spacer segment and shaft consistent with the mitral valve implant according to the present disclosure;

FIG. **7** is a perspective view of another embodiment of the spacer consistent with the mitral valve implant according to the present disclosure;

FIG. **8** is a perspective view of one embodiment of a collapsed spacer segment partially disposed within a lumen of an implant delivery system;

FIG. **9** is an end view of the collapsed spacer segment within the lumen consistent with FIG. **8**; and

FIG. **10** depicts one embodiment of a mitral valve implant including a plurality of individual segments disposed within an implant delivery system consistent with the present disclosure.

DESCRIPTION

Referring to FIG. **1**, a perspective view of one embodiment of a mitral valve implant **10** is depicted. As shown, mitral valve implant **10** may generally include a spacer or valve body portion **12** which may be coupled to a shaft **14**. The shaft **14** may be coupled to at least one anchor portion **16** configured to couple, attach, and/or otherwise secure the mitral valve implant **10** to native coronary tissue. In general, at least a portion of the spacer **12** may be configured to be disposed proximate a mitral valve **18** as generally shown in FIGS. **2** and **3** such that the mitral valve implant **10** may interact and/or cooperate with at least a portion of the native mitral valve **18** to reduce and/or eliminate excessive regurgitation through the mitral valve **18**.

The spacer **12** of the mitral valve implant **10** shown in FIG. **1** may comprise at least two individual segments or components **20***a*-**20***n*. As will be explained in greater detail hereinbelow, the plurality of segments **20***a*-**20***n* may be configured to be individually delivered and assembled proximate an implant site of the mitral valve implant **10** to form a spacer **12** having an overall size and shape configured to accommodate, at least in part, a patient's anatomy, etiology of valve regurgitation, and/or the limitations of the implant delivery system. The plurality of segments **20***a*-**20***n* may be configured to form a mitral valve implant **10** having a spacer **12** with at least one cross-sectional dimension that is larger than the internal cross-sectional dimensions of the implant delivery system used to deliver the mitral valve implant **10**. The plurality of segments **20***a*-**20***n* may also allow a mitral valve implant **10** to be constructed including a spacer **12** having an external size,

contour, and shape based on, at least in part, the patient's anatomy and etiology of the regurgitate valve. As such, the mitral valve implant **10** according to one aspect of the present disclosure may provide an enhanced sealing surface for the leaflets **19** of the mitral valve **18** for reducing and/or eliminating excessive regurgitation.

As can be seen, the spacer **12** may be comprised of at least two segments **20***a*-**20***n* that may be coupled to each other and, ultimately, to the shaft **14**. Consequently, a mitral valve implant **10** according to one embodiment of the present disclosure may be built-up or constructed from multiple segments **20***a*-**20***n* such that the resulting, constructed spacer **12** may have various cross-sectional shapes, sizes, configurations, or contours based on, at least in part, the patient's anatomy and etiology of the regurgitant valve. The cross-sectional shapes, sizes, configurations, or contours of the resulting spacer **12** may be varied by design and by quantity of the plurality of segments **20***a*-**20***n*. Moreover, a mitral valve implant **10** may be constructed including a spacer **12** having at least one external cross-sectional dimension that may be larger than the internal cross-sectional dimensions of the implant delivery system.

According to one aspect, one embodiment of an exploded, unassembled mitral valve implant **10** and spacer **12** is shown in FIG. **4**. In the illustrated embodiment, the plurality of segments **20***a*-**20***n* are shown having a generally tubular or cylindrical shape. However, one or more of the segments **20***a*-**20***n* may include other shapes and/or configurations. The overall shape/configuration of each of the segments **20***a*-**20***n* may be varied such that the spacer **12**, when constructed, provides a desired outer surface for interacting and/or cooperating with at least a portion of the native mitral valve **18** to reduce and/or eliminate excessive regurgitation through the mitral valve **18**. Moreover, the overall shape/configuration of each of the segments **20***a*-**20***n* may also be varied such to facilitate delivery of the plurality of segments **20***a*-**20***n* through the implant delivery device to the implant site.

For example, one or more of the segments **20***a*-**20***n* of the spacer **12** may include a symmetrical or non-symmetrical geometry. At least one segment **20***a*-**20***n* may also have a tapered and/or a bell-like shape. In another aspect, one or more of the segments **20***a*-**20***n* may be configured to be disposed substantially concentric with an adjacent segment **20** and/or the shaft **14**. Alternatively, one or more of the segments **20***a*-**20***n* may be configured to be non-concentric with an adjacent segment **20** and/or the shaft **14**.

According to another aspect, one or more of the segments **20***a*-**20***n* may be configured to be disposed substantially coextensively with one or more adjacent segments **20**. Alternatively, at least one of the segments **20***a*-**20***n* may be configured to be non-coextensive with one or more adjacent segments **20**. For example, at least one segment **20** may be configured to be disposed about only a portion of an adjacent segment **20**. In one instance, one or more of the segments **20***a*-**20***n* may be configured such that a single surface of a segment **20** is in substantially direct contact with at least a portion of the surfaces of two or more adjacent segments **20**. For example, a first segment **20***a*, FIG. **5**, may include a surface **28** having a first portion **29** which is in substantially direct contact with at least a portion of the surface **31** of a first adjacent segment **20***b* and a second portion **31** which is in substantially direct contact with at least a portion of a surface **33** of a second adjacent segment **20***c*. As shown, the first segment **20***a* may include an outer or exterior surface **28** that substantially directly contacts two adjacent segments **20***b* and **20***c*. Those skilled in the art may now appreciate that the surface **28** may also include an inner or interior surface of the first segment **20***a*.

According to one aspect, at least one of the plurality of segments **20***a*-**20***n*, FIG. **4**, may be coupled, mounted, or otherwise secured to at least a portion of the shaft **14** using any known technique and/or device. In the illustrated embodiment, a first segment **20***a* may be coupled to a distal end **13** of the shaft **14** generally opposite the anchor portion **16**. However, other configurations are also possible. For example, the shaft **14** may extend longitudinally beyond the spacer **12** in both directions as generally shown in FIG. **1**. For instance, one or more segments **20***a*-**20***n* may be disposed proximate a central region of the shaft **14**. Additionally, two or more segments **20***a*-**20***n* may be coupled, mounted, or otherwise secured to at least a portion of the shaft **14**.

One or more segments **20***a*-**20***n* may be coupled to at least a portion of the shaft **14** by way of an adhesive or cement (for example, but not limited to, a biologically acceptable adhesive or cement), bonding/molding (for example, but not limited to, overmolding and the like), or welding (for example, but not limited to, ultrasonic welding or the like). The segments **20***a*-**20***n* may also be coupled to at least a portion of the shaft **14** using a fastening mechanism. The fastening mechanism may substantially fix the position of one or more of the segments **20***a*-**20***n* and the spacer **12** with respect to the mitral valve implant **10** (and specifically with respect to the shaft **14**). According to another aspect, the fastening mechanism may allow one or more of the segments **20***a*-**20***n* and the spacer **12** to move relative to the shaft **14**. For example, the fastening mechanism may allow the one or more of the segments **20***a*-**20***n* and spacer **12** to move generally along the longitudinal axis L and/or radially with respect to the shaft **14**.

One example of a fastening mechanism may include one or more detents or protrusions **19** as shown in FIG. **6**. The detents **19** may be provided as a spring-biased detent, a resilient/elastically deformable detent, or a substantially solid detent. As illustrated, the shaft **14** may be provided with one or more detents **19** extending generally outwardly from the shaft **14**. Alternatively (or in addition), one or more of the segments **20***a*-**20***n* may be provided with detents **19** for coupling with the shaft **14**. One or more of the detents **19** may be integrally formed with the shaft **14** and/or segment **20**. Furthermore, one or more of the detents **19** may be provided as a separate feature coupled to and/or formed on the shaft **14** and/or segment **20**.

In an embodiment in which one or more of the detents **19** are formed as a spring-biased or resilient/elastically deformable detent coupled to the shaft **14**, the segment **20***a* may be slidably coupled to the shaft **14** by pressing the segment **20***a* over at least one of the detents **19**, which may at least partially retract or deform to permit passage of at least one of the detents **19** through an opening **21** and into a cavity **23** of the segment **20***a*. The spring-biased or resilient/elastically deformable detent **19** may at least partially expand and/or recover, thereby resisting passage of the one or more spring-biased detents **19** back through the opening **21**. For example, the shaft **14** and/or the cavity **23** may be provided with a recessed region (not shown) configured to at least partially receive and engage the detent **19**. The size and shape of the detent **19**, the opening **21**, cavity **23**, and/or recessed region as well as the force provided by the spring-biased or resilient detent may be configured to engage each other such that the segment **20***a* may either permit movement of the segment **20***a* or substantially prevent movement of the segment **20***a*.

In an embodiment in which one or more of the detents **19** are formed as a substantially solid detent coupled to the shaft **14**, the segment **20***a* may be slidably coupled to the shaft **14** by pressing the segment **20***a* over at least one of the detents **19**. The opening **21** of the segment **20***a* may at least partially

elastically deform to permit passage of at least one of the detents **19** into the cavity **23**. Once the detent **19** has been pressed through the opening **21**, the opening **21** may at least partially elastically recover, thereby resisting passage of the detent **19** back through the opening **21**. Again, the size and shape of the detent **19**, the opening **21**, and/or cavity **23**, as well as the elastic properties, may be configured to engage each other such that the segment **20***a* may either permit movement of the segment **20***a* or substantially prevent movement of the segment **20***a*. Various other arrangements may be employed for providing detents on the shaft **14** and/or the segments **20***a*-**20***n* for coupling, controlling and/or limiting translation of the spacer **12** along the shaft **14**. It will be appreciated that the segments **20***a*-**20***n* may be selectively removable from the shaft **14** by applying a force along the longitudinal axis L sufficient to overcome the holding force of the detents **19**.

At least one segment **20***b*-**20***n* may be configured to be at least partially disposed about and coupled to the first segment **20***a* as generally depicted in FIGS. **1** and **5**. Additional segments **20***n* may also be configured to be at least partially disposed about and coupled to an inner, adjacent segment (for example, segment **20***b*). As discussed above, the number and configuration of segments **20***a*-**20***n* may be based on, at least in part, the patient's anatomy and etiology of the regurgitant valve, as well as the physical limitations of the implant delivery system (such as, but not limited to, the internal cross-sectional dimensions of the implant delivery system).

According to one aspect, the additional segments **20***b*-**20***n* may include an internal cavity **40**, for example, as seen in FIG. **4**, which may be configured to at least partially receive at least a portion of an inner, adjacent segment **20**. As used herein, the term "inner, adjacent segment" or the like is intended to refer to a segment **20** which is at least partially disposed radially inwardly, e.g., generally towards the shaft **14**. Additionally, the term "additional segments" and the like is intended to refer to segments which are at least partially coupled to at least one inner, adjacent segment. For example, in the embodiment illustrated in FIG. **4**, a second segment **20***b* may include a cavity **40'** configured to at least partially receive the first segment **20***a*. Optionally, a third segment **20***n* may include a cavity **40"** configured to at least partially receive the second segment **20***b*. While three segments **20** are shown, the spacer **12** may include a greater or less number of segments **20**.

One or more of the cavities **40** may have an internal contour configured to substantially correspond to the outer surface **42** of one or more of the inner, adjacent segments **20** to be received therein. For example, the cavity **40** may include an inner surface **44** that is substantially coextensive with the outer surface **42** of one or more of the inner, adjacent segments **20** to be received therein. One or more of the cavities **40** and outer surfaces **44** may be configured to provide an interference and/or friction fit. For example, one or more of the cavities **40** may be deformable such that the cavity **40** stretches (either permanently or resiliently deformable) to receive at least a portion of the inner, adjacent segments **20** to be received therein.

One or more of the cavities **40** and/or segments **20***a*-**20***n* may be configured to reduce or substantially eliminate the rotation of one segment **20** relative to an adjacent segment **20**. For example, a cavity **40** and an inner, adjacent segment **20** may be provided with a non-cylindrical shape such that the inner, adjacent segment **20** may be received in the cavity **40** in substantially only a single orientation. Other configurations for reducing and/or eliminating the rotational movement of adjacent segments **20** are also possible.

While the illustrated cavities **40** are shown having a configuration which may substantially entirely circumscribe at least a portion of the outer surface **42** of an inner, adjacent segment **20** to be received therein, one or more of the cavities **42** may be configured to be disposed only about a portion of the outer surface **42** of the inner, adjacent segment **20** to be received therein. For example, one or more of the cavities **40** may be configured to be radially disposed about less than **360** degrees of the outer surface **42** of the inner, adjacent segment **20** to be received therein as shown in FIG. **7**.

In any case, the additional segments **20***b*-**20***n* may be coupled to an inner, adjacent segment **20** using any known technique and/or device. For example, the additional segments **20***b*-**20***n* may be coupled to an inner, adjacent segment **20** using an interference fit between the cavity **40** and the outer surface **42** of the inner, adjacent segment **20** as discussed above. Alternatively (or in addition), one or more of the additional segments **20***b*-**20***n* may be coupled to an inner, adjacent segment **20** using an adhesive or cement (for example, but not limited to, a biologically acceptable adhesive or cement), bonding/molding (for example, but not limited to, overmolding and the like), or welding (for example, but not limited to, ultrasonic welding or the like). The additional segments **20***b*-**20***n* may also be coupled to at least a portion of an inner, adjacent segment **20** using a fastening mechanism. The fastening mechanism may substantially fix the position of one or more of the segments **20***a*-**20***n* with respect to the mitral valve implant **10**. According to another aspect, the fastening mechanism may allow one or more of the segments **20***a*-**20***n* and the spacer **12** to move relative to the shaft **14**. For example, the fastening mechanism may allow the one or more of the segments **20***a*-**20***n* and spacer **12** to move generally along the longitudinal axis L and/or radially with respect to the shaft **14**.

One example of a fastening mechanism may include one or more detents or protrusions **19** as shown in FIG. **4**. The detents **19** may be disposed out the outer surface **42** of one or more of the segments **20***a*-**20***n* and/or may be disposed at least partially within the cavity **40** of one or more of the segments **20***a*-**20***n*. The detents **19** may include any of the various detent configurations discussed above such as, but not limited to, spring-biased detents, resilient/elastically deformable detents, or substantially solid detents.

According to one aspect, at least a portion of the body **24** of one or more of the plurality of segments **20***a*-**20***n* may be expandable, retractable, collapsible and/or reducible in volume to facilitate percutaneous and/or transluminal delivery of the mitral valve implant **10**. In such a manner, one or more of the segments **20***a*-**20***n* of the mitral valve implant **10** may include a collapsible member, which may be reduced in volume and/or reduced in maximum cross-section during delivery to the heart and/or during placement and/or attachment of the anchor **16** to native coronary tissue. After delivery to the heart, the segments **20***a*-**20***n* may be expanded, inflated, and/or otherwise increased in volume or size. Accordingly, the mitral valve implant **10** may be delivered to an implantation site via a smaller diameter catheter, and/or via smaller vessels, than would otherwise be required.

The deformable segments **20***a*-**20***n* may be collapsed to a reduced size, which may, for example, facilitate loading the mitral valve implant **10** into a lumen **51** of a catheter delivery system **53** as generally shown in FIGS. **8** and **9**. Such a catheter delivery system **53** may be suitable for transluminal delivery of a mitral valve implant **10**, including the segments **20***a*-**20***n*, to the heart as will be explained further below. In addition to being collapsed, the segments **20***a*-**20***n* may be deformed to facilitate loading into a catheter delivery system

53. For example, the segments **20***a*-**20***n* may be collapsed and may be rolled and/or folded to a generally cylindrical shape, allowing the segments **20***a*-**20***n* to be loaded in a catheter having a generally circular lumen **51** as generally depicted in FIGS. **8** and **9**.

A collapsed and/or rolled or folded segments **20***a*-**20***n* may be inflated, restoring the segments **20***a*-**20***n* to expanded configuration. For example, a collapsed and/or rolled or folded segments **20***a*-**20***n* may be inflated and restored to an expanded configuration once the mitral valve implant **10** has been delivered to the heart and deployed from a catheter delivery system **53**. Inflating the segments **20***a*-**20***n* may be carried out by introducing a fluid, such as saline, into the at least one cavity of the segments **20***a*-**20***n*. In addition to a liquid, such as saline, the segments **20***a*-**20***n* may be inflated with a setting or curable fluid. The setting or curable fluid may set and/or be cured to a solid and/or semi-solid state within the cavity of the segments **20***a*-**20***n*. An example of such a material may be a thermoset polymer resin, a gel material, such as silicone gel, etc.

At least a portion of the segments **20***a*-**20***n* may also be constructed from a shape-memory material. For example, at least a portion of the segments **20***a*-**20***n* may include a shape-memory alloy such as, but not limited to, copper-zinc-aluminum, copper-aluminum-nickel, and nickel-titanium (NiTi) alloys. The shape-memory alloy may include either one-way or two-way shape memory and may be introduced in to the delivery catheter lumen **51** having a shape which does not exceed the interior dimensions of the delivery catheter lumen **51**. For example, the segments **20***a*-**20***n* may have a generally elongated or generally helical shape. Upon delivery to proximate the mitral valve **18**, the shape-memory segments **20***a*-**20***n* may be heated to cause the segments **20***a*-**20***n* to deform into the desired shape for installation.

Alternatively (or in addition), one or more of the plurality of segments **20***a*-**20***n* may have generally solid geometry. As used herein, the phrases "generally solid geometry," "substantially solid geometry," or the like are intended to mean a geometry having an outer surface that defines a substantially fixed or constant volume. That is, a volume of the segments **20***a*-**20***n* does not substantially change before and after implantation of the mitral valve implant **10**. A "generally solid geometry" may include, without limitation, a solid, semi-solid, or porous (e.g., micro- or nano-scale pores) material. The use a plurality of segments **20***a*-**20***n* having a generally solid geometry may reduce the complexity and/or cost associated with the fabrication and/or implantation of the mitral valve implant **10**. According to one embodiment, a segment **20** having a generally solid geometry may be provided having an outer cross-section which is no larger than the inner cross-section of the delivery lumen **51**. For example, the first segment **20***a* may be provided having a generally solid geometry while additional segments **20***n* may be provided having a deformable geometry.

One or more of the segments **20***a*-**20***n* may also be coupled to the shaft **14** prior to delivery of the mitral valve implant **10** to the heart. In such an embodiment, the segments **20***a*-**20***n* coupled to the shaft **14** may be provided having external cross-sectional dimensions (when either expanded or collapsed) that are no larger than the internal cross-sectional dimensions of the implant delivery system.

At least a portion of the plurality of segments **20***a*-**20***n* may be constructed from a synthetic and/or biological material depending on the application and the patient condition. The segments **20***a*-**20***n* may include a plurality of layers. For example, the segments **20***a*-**20***n* may include an open or closed cell foam substrate (for example, but not limited to, Invalon polyvinyl) and an outer layer of a material that is biologically acceptable. The outer layer may also include a material that is soft and/or deformable (either permanently or resiliently deformable) that may reduce and/or eliminate further scarring and/or damage to the leaflets **19** of the mitral valve **18**. According to one aspect, the substrate of the segments **20***a*-**20***n* may be coated with or formed substantially from a silicone urethane composite such as, but not limited to, Elasteon or the like.

The plurality of segments **20***a*-**20***n*, when assembled as generally depicted in FIG. **1**, may form a mitral valve implant **10** including a spacer **12** having an outer surface **27** that may be configured to interact and/or cooperate with at least a portion of the native mitral valve **18** (e.g., the leaflets **19**) to reduce and/or eliminate excessive regurgitation as illustrated in FIGS. **2** and **3**. According to one aspect, the mitral valve implant **10** (and in particular, the plurality of segments **20***a*-**20***n* forming the spacer **12**) may be selected from a range or set of sizes and shapes. For example, a "standard set" may be utilized where a set of "consensus" sizes and shapes of segments **20***a*-**20***n* are pre-manufactured and provided to health care providers as a kit. This particular aspect has the advantage of being the most uniform and therefore the least expensive for the patient. Alternatively, a "custom design" may be fabricated where the exact size and shape of one or more of the segments **20***a*-**20***n* is determined only after precise and/or detailed measurements of the dimensions of a patient's mitral valve **18** are obtained. As a result, the overall size and/or shape of the spacer **10** may be contoured to a specific patient if necessary.

In practice, the plurality of segments **20***a*-**20***n* may be aligned serially along at least a portion of the shaft **14** (i.e., one segment **20***a* after another segment **20***b*) and inserted into the implant delivery system **53**, a portion of which is generally depicted in FIG. **10**. As mentioned above, the implant delivery system **53** may include a catheter **55** having a generally circular inner lumen **51**. Those skilled in the art will recognize that the catheter **55** may include any catheter known to those skilled in art. While only a single lumen **51** is shown for clarity, the catheter **55** may include a plurality of lumens **51**. According to one aspect, one or more of the segments **20***a*-**20***n* may have an outer cross-section that is larger than the internal cross-section of the lumen **51**. In such a case, the plurality of segments **20***a*-**20***n* may be deformed or otherwise reduced in cross-section and/or volume such that each of the segments **20***a*-**20***n* may fit within the lumen **51**.

Once loaded into the delivery catheter system **53**, the mitral valve implant **10** may be moved or delivered proximate the implant site using any device know to those skilled in the art. While moving the mitral valve implant **10** through the delivery catheter system **53**, the plurality of segments **20***a*-**20***n* may be individually rotated to facilitate movement of the plurality of segments **20***a*-**20***n*. This may be particularly useful to facilitate navigating the plurality of segments **20***a*-**20***n* about curves, bends or the like in the catheter **55**. The shaft **14** may include a generally rigid shaft and/or a generally flexible shaft.

According to another aspect, shaft **14** and the plurality of segments **20***a*-**20***n* may be separately loaded into the catheter delivery system **53** and delivered to the implant site. According to this aspect, the shaft **14** (which may optionally include the anchor portion **16**) may be first loaded into the catheter delivery system **53** and the plurality of segments **20***a*-**20***n* may be subsequently serially loaded into the catheter delivery system **53**. Of course, the order of loading and/or delivering the shaft **14** and/or plurality of segments **20***a*-**20** to the implant site may be changed.

Once the shaft **14** and the plurality of segments **20***a*-**20***n* are proximate the implant site, the plurality of segments **20***a*-**20***n* may be disposed or arranged about the shaft **14** and inner, adjacent segments **20***b*-**20***n* to construct a spacer **12** having a desired size and shape. While the spacer **12** is illustrated having a generally cylindrical outer surface, the size and shape of the spacer **12** and each of the plurality of segments **20***a*-**20***n* may be varied by design and by quantity to accommodate the patient anatomy, etiology, and limitations of the delivery system **100** (e.g., the internal dimensions of the catheter lumen).

According to an embodiment, a first segment **20***a* of the spacer **12**, FIG. **1**, may be slidably coupled to the shaft **14**. The segment **20***a* may include an opening **46** extending from a first end **44** of the spacer **12**, through the spacer **12**, and to a second end **40**. In one such embodiment, the opening **46** may extend generally axially through the spacer **12** and may be sized to slidably receive at least a portion of the shaft **14** therethrough. The shaft **14** may include one or more stops **48**, **50**. The stops **48**, **50** may be sized and/or shaped to control and/or restrict translation of the spacer **12** along the shaft **14** beyond the respective stops **48**, **50**. In this manner, in the illustrated embodiment, translation of the spacer **12** along the shaft **14** may be restricted to the expanse of the shaft **14** between the stops **48**, **50**.

One or more of the stops **48**, **50** may be integrally formed with the shaft **14**. Furthermore, one or more of the stops **48**, **50** (such as, but not limited to, stop **50**) may be provided as a separate member coupled to and/or formed on the shaft **14**. In an embodiment in which one or more of the stops **48**, **50** are integrally formed with the shaft **14**, the spacer **12** may be slidably coupled to the shaft **14** by pressing the spacer **12** over at least one of the stops **48**, **50**, which may at least partially elastically deform the opening **46** to permit passage of at least one of the stops **48**, **50**. Once the one or more of the stops **48**, **50** have been pressed through the opening **46**, the opening **46** may at least partially elastically recover, thereby resisting passage of the one or more stops **48**, **50** back through the opening **46**. Various other arrangements may be employed for providing stops on the shaft **14** and/or for controlling and/or limiting translation of the spacer **12** along the shaft **14**.

The anchor portion **16** may include a helical member **52** coupled to the shaft **14**. As shown, the helical member **52** may be loosely wound such that adjacent turns of the helical member **52** do not contact one another, for example resembling a corkscrew-type configuration. The anchor portion **16** may be engaged with tissue by rotating the anchor portion **16** about the axis of the helical member **52**, thereby advancing the anchor portion **16** into tissue. Consistent with such an embodiment, the anchor portion **16** may resist pulling out from the tissue. The anchor portion **16** may be provided as an extension of the shaft **14** wound in a helical configuration. Consistent with related embodiments, the anchor portion **16** may be formed as a separate feature and may be coupled to the shaft **14**, e.g., using mechanical fasteners, welding, adhesive, etc.

According to various alternative embodiments, the anchor portion **16** may include various configurations capable of being coupled to and/or otherwise attached to native coronary tissue. For example, the anchor portion **16** may include one or more prongs adapted to pierce coronary tissue and to alone, or in conjunction with other features, resist removal of the anchor portion **16** from tissue. For example, the anchor portion **16** may include a plurality of prongs which may engage native coronary tissue. According to various other embodiments, the anchor portion **16** may include features that may facilitate attachment by suturing. Exemplary features to facilitate suturing may include rings or openings, suture penetrable tabs, etc. Various other anchor portions **16** that may allow attachment or coupling to native coronary tissue may also suitably be employed in connection with the present disclosure.

Turning to FIGS. **2** and **3**, the mitral valve implant **10** is shown implanted within a heart **102**. The mitral valve implant **10** may be disposed at least partially within the left ventricle **64** of the heart **102**. As shown, the anchor portion **16** may be engaged with native coronary tissue within and/or adjacent to the left ventricle **64**. The shaft **14**, coupled to the anchor portion **16**, may extend into the left ventricle **64**. The shaft **14** may further extend at least partially within the mitral valve **18**, i.e., the shaft **14** may extend at least partially between the cusps or leaflets **19** of the mitral valve **18**, and may also extend at least partially into the left atrium **62**. The spacer **12** of the mitral valve implant **10** may be positioned at least partially within the left ventricle **64** with the bottom portion **44** within the left ventricle **64** and with the upper portion **40** positioned at least partially within and/or pointed towards the left atrium **62**.

FIG. **2** depicts the heart **102** in a condition in which the pressure of blood within the left atrium **62** is at equal to, or higher than, the pressure of blood within the left ventricle **64**, e.g., during contraction of the left atrium **62**. As shown, when the pressure of blood within the left atrium **62** is greater than or equal to the pressure of blood within the left ventricle **64**, blood may flow from the left atrium **62** into the left ventricle **64**. The pressure differential and/or the flow of blood from the left atrium **62** to the left ventricle **64** may slidably translate the spacer **12** along the shaft **14** toward the left ventricle **64**, in the direction of blood flow between the chambers.

Sliding translation of the spacer **12** along the shaft **14** may at least partially withdraw the spacer **12** from the mitral valve **18** to an open position, as shown. When the spacer **12** is at least partially withdrawn from the mitral valve **18**, a passage may be opened between the spacer **12** and the mitral valve **18**, allowing blood to flow from the left atrium **62** to the left ventricle **64**. Translation of the spacer **12** away from the mitral valve **18** may be controlled and/or limited by the stop **48**. In the open position, the stop **48** may maintain the spacer **12** in general proximity to the mitral valve **18** while still permitting sufficient clearance between the mitral valve **18** and the spacer **12** to permit adequate blood flow from the left atrium **62** to the left ventricle **64**. Additionally, the flow of blood from left atrium **62** to the left ventricle **64** may cause the mitral valve **18** to flare and/or expand outwardly away from the mitral valve implant **10**, permitting blood flow between the implant **10** and the cusps **19** of the mitral valve **19**.

As the left ventricle **64** contracts, the pressure of blood in the left ventricle **64** may increase such that the blood pressure in the left ventricle **64** is greater than the blood pressure in the left atrium **62**. Additionally, as the pressure of the blood in the left ventricle **64** initially increases above the pressure of the blood in the left atrium **62**, blood may begin to flow towards and/or back into the left atrium **62**. The pressure differential and/or initial flow of blood from the left ventricle **64** into the left atrium **62** may act against the spacer **12** and may translate the spacer **12** toward the left atrium **104**. For example, pressurized blood within the left ventricle **64** may act against the bottom of the spacer **12** inducing sliding translation of the spacer **12** along the shaft **14** toward the left atrium **62**.

In the closed position as shown in FIG. **3**, the spacer **12** may be translated toward and/or at least partially into the left atrium **62**. At least a portion of the spacer **12** may interact with, engage, and/or be positioned adjacent to at least a portion of the mitral valve **18**. For example, at least a portion of

at least one cusp **19** of the mitral valve **18** may contact at least a portion of the spacer **12**. Engagement between the spacer **12** and the mitral valve **18** may restrict and/or prevent the flow of blood from the left ventricle **64** back into the left atrium **62**.

In addition to the translation of the spacer **12**, the mitral valve **18** may also at least partially close around the spacer **12**, thereby also restricting and/or preventing the flow of blood from the left ventricle **64** to the left atrium **62**. For example, as mentioned above, at least a portion of one or both of the cusps **19** of the mitral valve **18** may contact at least a portion of the spacer **12**. In some embodiments, as the pressure of the blood in the left ventricle **64** increases, the pressure against the bottom **44** of the spacer **12** may increase. The increase in pressure against the bottom **44** of the spacer **12** may, in turn, increase the engagement between the spacer **12** and the mitral valve **18**.

Sliding translation of the spacer **12** toward the left atrium **62** may at least partially be controlled and/or limited by the stop **50** coupled to the shaft **14**. Additionally, translation of the spacer **12** toward the left atrium **62** may be at least partially limited and/or controlled by engagement between the spacer **12** and the mitral valve **18**. One or both of these restrictions on the translation of the spacer **12** may, in some embodiments, prevent the spacer **12** from passing fully into the left atrium **62**. Furthermore, the diameter and/or shape of the spacer **12** may limit and/or restrict the movement of the spacer **12** into the left atrium **62**.

The preceding embodiment may, therefore, provide a mitral valve implant that is slidably translatable relative to the mitral valve to reduce and/or eliminate regurgitation. Additional embodiments of a mitral valve implant are described in co-pending U.S. patent application Ser. No. 11/258,828, entitled "Heart Valve Implant" filed on Oct. 26, 2005, U.S. patent application Ser. No. 11/748,147, entitled "Safety for Mitral Valve Plug" filed on May 14, 2007, U.S. patent application Ser. No. 11/748,138, entitled "Solid Construct Mitral Spacer" filed on May 14, 2007, and U.S. patent application Ser. No. 11/748,121, entitled "Balloon Mitral Spacer" filed on May 14, 2007, all of which are hereby incorporated by reference. For example, the mitral valve implant may include a generally stationary spacer and may include more than one anchoring portions.

The implant herein has been disclosed above in the context of a mitral valve implant. An implant consistent with the present disclosure may also suitably be employed in other applications, e.g., as an implant associated with one of the other valves of the heart, etc. The present invention should not, therefore, be construed as being limited to use for reducing and/or preventing regurgitation of the mitral valve.

According to one aspect, the present disclosure features a heart valve implant. The heart valve implant may include a shaft extending generally along a longitudinal axis of the heart valve implant. A spacer may comprise a plurality of individual segments including at least a first segment configured to be coupled to the shaft and at least a second segment configured to be coupled to a least a portion of an outer surface of the first segment. The plurality of individual segments may define an outer surface of the spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through the heart valve in a closed position. The heart valve implant may also include at least one anchor configured to be coupled to a first end region of the shaft.

According to another aspect, the present disclosure features a method of introducing a heart valve implant with respect to a heart valve. The method may include providing a heart valve implant comprising a shaft, at least one anchor configured to be coupled to the shaft, and a spacer including a plurality of individual segments including a first and at least a second segment. The plurality of individual segments may define an outer surface of the spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through the heart valve in a closed position. The plurality of individual segments may be serially aligned. The shaft and the first and the plurality of segments may be percutaneously delivered proximate the heart and the first segment may be coupled to the shaft. The second segment may be coupled to at least a portion of an outer surface of the first segment to define the spacer and the heart valve implant may be secured within the heart.

According to yet another aspect, the present disclosure features a heart valve implant system. The heart valve implant system may comprise a catheter including a lumen and a heart valve implant. The heart valve implant may comprise a shaft extending generally along a longitudinal axis of the heart valve implant. A spacer may comprise a plurality of individual segments including at least a first segment configured to be coupled to the shaft and at least a second segment configured to be coupled to a least a portion of an outer surface of the first segment. The second segment may include at least one cross-sectional dimension that is larger than an internal cross-section of the lumen. The plurality of individual segments may define an outer surface of the spacer configured to interact with at least a portion of at least one cusp of a heart valve to at least partially restrict a flow of blood through the heart valve in a closed position. At least one anchor may be configured to be coupled to a first end region of the shaft.

As mentioned above, the present disclosure is not intended to be limited to a system or method which must satisfy one or more of any stated or implied object or feature of the present disclosure and should not be limited to the preferred, exemplary, or primary embodiment(s) described herein. The foregoing description of a preferred embodiment of the present disclosure has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the present disclosure to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiment was chosen and described to provide the best illustration of the principles of the present disclosure and its practical application to thereby enable one of ordinary skill in the art to utilize the present disclosure in various embodiments and with various modifications as is suited to the particular use contemplated. All such modifications and variations are within the scope of the present disclosure as determined by the claims when interpreted in accordance with breadth to which they are fairly, legally and equitably entitled.

What is claimed is:

1. A heart valve implant comprising:

a shaft extending generally along a longitudinal axis of said heart valve implant;

a spacer configured to interact with at least a portion of at least one cusp of a patient's heart valve to at least partially restrict a flow of blood through said heart valve in a closed position, said spacer comprising at least a first segment configured to be coupled to said shaft while disposed within a patient's heart;

a fastener comprising at least one detent configured to couple said shaft with said at least one segment of the spacer; and

at least one anchor configured to be coupled to a first end region of said shaft.

2. A heart valve implant according to claim 1, wherein said at least one detent comprises a resilient detent configured to resiliently deform and at least partially recover.

3. A heart valve implant according to claim 1, wherein said at least one detent comprises a resilient detent configured to resiliently deform and at least partially recover.

4. A heart valve implant according to claim 2, wherein said at least one detent comprises a spring-biased detent.

5. A heart valve implant according to claim 2, wherein said at least one detent comprises a substantially solid detent.

6. A heart valve implant according to claim 1, wherein said spacer further comprises at least a second segment configured to be coupled to at least a portion of an outer surface of said first segment.

7. A heart valve implant according to claim 5, wherein at least one of said plurality of individual segments includes a fastener for coupling with an adjacent segment.

8. A heart valve implant according to claim 1, wherein said at least said first segment comprises an expandable portion.

9. A heart valve implant according to claim 7, wherein said expandable portion comprises an inflatable bladder.

10. A heart valve implant according to claim 7, wherein said expandable portion comprises a shape memory material configured to recoverably deform.

11. A heart valve implant system comprising:

a catheter including a lumen; and

a heart valve implant comprising:

a shaft extending generally along a longitudinal axis of said heart valve implant;

a spacer configured to interact with at least a portion of at least one cusp of a patient's heart valve to at least partially restrict a flow of blood through said heart valve in a closed position, said spacer comprising at least one segment configured to be coupled to said shaft; and

at least one anchor configured to be coupled to a first end region of said shaft.

12. A heart valve implant system according to claim 11, wherein said heart valve implant further comprises a fastener configured to couple said shaft with said at least one segment.

13. A heart valve implant system according to claim 12, wherein said fastener includes at least one detent.

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